

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF APPEALS**

Appellant: Ian Carr et al.    }  
Serial No: 10/827,434    }  
Filed: April 20, 2004    }  
For: TAMPER EVIDENT VACUUM    }  
TUBE HOLDER ASSEMBLY    }  
AND NEEDLE HUB ASSEMBLY    }  
THEREFOR    }  
  }  
  }

**APPEAL BRIEF**

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### **REAL PARTY IN INTEREST**

The real party in interest of the instant application is Smiths Medical ASD, Inc., to whom the inventors assigned their invention per an assignment recorded April 20, 2004 on Reel 015236, Frame 0005 of the Assignment Branch of the US PTO.<sup>1</sup>

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<sup>1</sup> At the time of the April 20, 2004 recordation, the name of the assignee was Portex, Inc. The name of the assignee has since been changed to the aforenoted Smiths Medical ASD, Inc. This change of name from Portex, Inc. to Smiths Medical ASD, Inc. was recorded October 26, 2004 on Reel 015926, Frame 0834 of the Assignment Branch of the US PTO.

**RELATED APPEALS AND INTERFERENCES**

The instant application is a CIP of application of 10/419,934 filed on April 22, 2003. The '934 application is under appeal, and has been assigned Appeal No. 2010-001315.

**STATUS OF CLAIMS**

Claims 1-3, 5-14, 16-18 and 20 have been finally rejected.

Claims 15, 19 and 21 have been deemed to be allowable if written in independent form, including all of the limitations of the base claim and any intervening claims to which they depend.

Claims 4 and 22-27 have been withdrawn from this application.

**STATUS OF AMENDMENTS**

No amendment was filed subsequent to the final rejection office action of July 6, 2010.

## **SUMMARY OF CLAIMED SUBJECT MATTER**

A. Independent claim 1 is directed to an apparatus that includes a one piece cylindrical body (4) having an opening (6) at one end through which a fluid storage tube is insertable, a neck (10), and an elongate needle cover (12) integrally joined to the neck at a weakened joint (28) so that the cover integrally extends from the cylindrical body [Figs 1-4; 0030-0034]. The apparatus further includes finger grasp means (80) coupled to the cover at a desired location along the length of the cover to amplify the torque force applied by a user to the cover when the user applies a predetermined torque to the finger grasp means to rotate the cover relative to the body to separate the cover from the neck at the weakened joint, the predetermined torque if applied anywhere along the length of the cover whereto the finger grasp means is not coupled would fail to separate the cover from the neck, the neck having an aperture dimensioned to accept a needle hub (48) [Figs 11-14; 0050-0059].

The apparatus of claim 1 therefore is directed to a one piece component defined by a body having a neck to which a cover is integrally attached at a weakened joint. The body is further defined to have an open end through which a fluid storage device may be inserted into the body, and the neck is further defined to have an aperture that is dimensioned to accept a needle hub. The cover has a finger grasp mechanism coupled thereto at a desired location that enables a user to readily separate the cover from the neck of the body at the weakened joint with a rotating force that otherwise would not have been sufficient to break the cover off the neck.

Thus, the claimed apparatus can have a thicker notched junction as its weakened joint to prevent inadvertent breaking off of the cover from the neck of the body during shipping or handling, and at the same time enables a user to separate the cover from the body by exerting a torque force substantially similar to that used for non-finger grasp means fitted one piece integral fluid tube storage device that has a body, neck and cover [0009].

B. Independent claim 11 relates to a needle holder assembly that includes:

(I) a cylindrical body (4)

that has an opening (6) at one end through which a fluid storage tube is insertable, a neck (10) having one lock mechanism (20A, 20B) formed transverse to a side

thereof, and an elongate cover (12) integrally extending from the neck and joined to the neck at a weakened joint (28) [Figs 1-4; 0030-0034],

(ii) finger grasp means (80)

that is fixedly mounted to a desired location along the length of the elongate cover having at least one wing (82, 84) that extends away from the elongate cover [Figs 11a-11d, 12-14; 0050-0054];

(iii) a needle hub assembly (70) [Figs 9 and 15-17]

that has a proximal section (42) and a distal section (40), a double ended needle (41) that extends through the distal and proximal sections, and an other lock mechanism (54A, 54B) formed at the outer surface of the proximal section [Figs 5-7].

In terms of the relationship among components i-iii, the needle hub assembly is fixedly fitted within the body with at least the proximal section fitted within the neck and the one and other lock mechanisms in a locking relationship [0042]; and the cover is separable from the neck at the weakened joint when a predetermined torque is applied to the wing relative to either the body or the neck [0057].

Claim 11 therefore is directed to a completely assembled needle holder assembly having the elements, per shown in Figs 15-17 sans the needle protection housing 72. Putting it simply, the assembly of claim 1 defines the one piece apparatus shown in Figs 1-4 having fitted within its body the needle hub assembly shown in Figs 5-7, with the proximal section of the needle hub of the assembly fitted within the neck of the body and the lock mechanisms at the neck and the needle assembly locked to each other. A finger grasp mechanism having at least one wing extending away from the cover is mounted to a desired location along the length of the cover to enable a user to apply a predetermined torque to the wing of the finger grasp mechanism to separate the needle cover from the neck of the body.

C. Independent claim 18 relates to a one piece molded needle holder (2) that includes a cylindrical body (4) having a cavity (8) and an opening (6) at one end through which a fluid storage tube is insertable to the cavity. The body ends with a neck (10) having at least one orifice (20A, 20B) formed transverse to a side thereof. The neck has an aperture (16) smaller in dimension than the cavity of the body. A needle cover (12) having a longitudinal length is integrally joined to and extends from the end of the neck away from

the body. A notch (30) is formed circumferentially about the junction where the neck is joined to the cover to effect a weakened joint (28). Finger grasp means (80) is coupled to a desired location along the length of the needle cover to enable a user to twist off the needle cover from the neck by applying a predetermined torque thereto [Figs 1-4 and 11a-11d to 17; 0030-0034 and 0050-00557].

Claim 18 therefore is directed to a one piece molded needle holder having a body that has an open end for accepting a fluid storage tube into its cavity. The body has a neck that has at least one orifice at a side and an aperture. A cover is integrally joined to the neck at a weakened joint formed by a notch. A finger grasp mechanism is coupled to the cover at a desired location along the former's length to enable a user to twist off the needle cover from the neck by applying a predetermined torque.

**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

- I. Whether claims 1, 5-6, 10-11 and 17-18 are anticipated under 35 USC 102(b) by Stevens (US 3,073,307).
- II. Whether claims 7-8 and 16 are unpatentable under 35 USC 103(b) as being obvious over Stevens.
- III. Whether claims 2-3, 14 and 20 are unpatentable under 35 USC 103(b) as being obvious over Stevens in view of Netherton et al. (US 4,900,309).
- IV. Whether claims 9, 13-14 are unpatentable under 35 USC 103(b) as being obvious over Stevens in combination with Newby et al. (US 6,436,086).

## **ARGUMENT**

### **I. 102(b) Rejection of Claims 1, 5-6, 10-11 and 17-18 Under Stevens (US 3,073,307)**

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. ... The identical invention must be shown in as complete detail as is contained in the claim. ... The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required.” MPEP 2131.01.

#### **Prior Art**

Stevens is directed to an “improved hypodermic needle hub structure” that “comprises a hypodermic needle hub section ... adapted to be fixedly mounted on the discharge outlet of a hypodermic syringe” (column 2, lines 54-58). In particular, Stevens discloses a needle hub assembly 10 that is made up of a hub body section 11 joined to a sheath portion 21 by a frangible section 19. A needle cannula 12 is fixedly secured to the hub body section 11 by means of a suitable ferrule or eyelet retaining ringed section 13 (column 3, lines 42-52; Figs. 1-4). The Stevens device therefore is a needle hub assembly per se that is to be mounted to the outlet end of a hypodermic syringe. A plurality of longitudinal projections 26 extend radially outwardly from the outer surface 24 of sheath 21 to provide finger gripping surface for the sheath (column 3, lines 69-73).

#### **Independent Claims**

The instant invention, as set forth in claim 1, is directed to an apparatus that has a one piece cylindrical body with an opening at one end through which a fluid storage tube is insertable. The inventive apparatus also has a neck that is integrally joined to an elongate needle cover at a weakened joint. By those features alone, claim 1 is not anticipated by Stevens, insofar as Stevens fails to disclose the one piece cylindrical body of claim 1. At best, Stevens discloses a neck and an elongate needle cover joined thereto. To argue that the hub body 11 of Stevens is equivalent to both the cylindrical body and the neck of the claimed apparatus is believed to be without merit insofar as the hub body 11 of the Stevens device is meant to be mounted to a discharge outlet of hypodermic syringe. In contrast, the cylindrical body of claim 1 has an opening through which a fluid storage tube is insertable. It is respectfully submitted that the outlet of a hypodermic syringe is not a fluid storage tube. That the cylindrical body is different from the neck in the apparatus

of claim 1 is supported by the limitation that the neck has an aperture that is dimensioned to accept a needle hub. In other words, for the instant invention, it is the neck to which the needle hub of a needle hub assembly is fitted. In contrast, the Stevens device itself is a needle hub assembly.

Claim 1 is further defined to include finger grasp means that is coupled to the cover at a desired location along the length of the cover. In contrast, the plurality of longitudinal projections 24 asserted by the examiner to be the same as the finger grasp means are part of the needle sheath 21. Thus, Stevens also fails to disclose the finger grasp means of claim 1.

Claim 11 is directed to an assembled needle holder assembly that has as its first component a cylindrical body that has an open end, a neck that has a lock mechanism at a side thereof, and an elongate cover that integrally extends from the neck at a weakened joint. The second component of the claim 11 needle holder assembly is the finger grasp means that is fixedly mounted to a desired location along the length of the needle cover with the finger grasp means having at least one wing that extends away from the elongate cover. The third component of the needle holder assembly is a needle hub assembly that has a proximal section and a distal section, with another lock mechanism formed at the outer surface of the proximal section. The needle holder assembly is configured to have the needle hub assembly fixedly fitted within the cylindrical body, with at least the proximal section of the needle hub assembly fitted within the neck of the cylindrical body so that the respective lock mechanisms at the neck and the needle hub assembly are in a locking relationship.

Nothing similar is disclosed by Stevens. To wit, as discussed above, Stevens discloses a needle hub assembly per se that has a hub body 11 and a sheath 21 integrally connected to each other by a frangible section 19. Even with respect to the embodiment shown in Fig. 5 which does show a double ended needle, Stevens nonetheless discloses a needle hub assembly with the needle hub 17 being enclosed by a cap 72, which is removed when the needle hub assembly is to be used, i.e., mounted to the outlet of a syringe (column 4, lines 31-34 and 66-75).

The examiner also asserts that the lock mechanisms of the needle holder assembly of claim 11 are met by the ferrule or ring section 13 of cannula 12 and the

projection/indentation 14 at the hub body 11. Yet claim 11 specifically requires that the neck has one lock mechanism “formed transverse to a side thereof” while the other lock mechanism is formed “at the outer surface of the proximal section” of the needle hub assembly. Putting it differently, it appears that for the “lock mechanisms” the examiner is equating the hub of cannula 12 to be a needle hub while equating needle hub body 11 to be the cylindrical body as well as the neck. If that were the case, then clearly there is no disclosure in the Stevens device of a lock mechanism formed transverse to a side of hub body 11. Moreover, the differences discussed above with respect to claim 1 are equally applicable herein, i.e., Stevens fails to disclose a cylindrical body having an opening through which a fluid storage tube is insertable, or finger grasp means that is fixedly mounted to a desired location along the length of the elongate cover.

Claim 18 is directed to a one piece molded needle holder that has a cylindrical body having a cavity and an opening at one end through which a fluid storage tube is insertable, and a neck having at least one orifice formed transverse to a side thereof and having an aperture smaller in dimension than the cavity. Stevens does not disclosure such a needle tube holder, for there is no opening at the hub body 11 through which a fluid storage tube is insertable, or a neck having an orifice formed transverse to a side thereof. There clearly is no “orifice” formed anywhere transverse to the needle hub assembly of Stevens. Claim 18 further defines the finger grasp means being coupled to a desired location along the length of the needle cover. As discussed above, Stevens fails to disclose such.

In view of the above discussion, it is submitted that the anticipation rejection of claims 1, 11, and 18 under Stevens is without merit and not sustainable.

### **Dependent Claims**

For this appeal, dependent claims that are discussed hereinbelow are to be adjudged separately from the patentability of the independent claims from which they depend.

Claim 6 depends from claim 1 and defines the needle hub (48) to be a part of the needle hub assembly (38) that comprises a base having a double ended needle (41). The needle hub is defined to include a proximal section (42) having at least one catch (54). When the needle hub of the needle hub assembly is fully inserted to the aperture, the

catch snappingly latches to a side orifice (20A, 20B) at the neck of the tube body [0042].

Stevens fails to disclose any orifice in his device. Accordingly, Stevens also fails to disclose the claimed catch that snappingly latches to the orifice at the neck when the needle hub assembly is fully inserted to the aperture of the neck.

## **II. 103b Rejection of Claims 7-8 and 16 Under Stevens**

The patentability of claims 7, 8 and 16 stands or falls with the patentability of the claims from which they depend.

## **III. 103b Rejection of Claims 2-3, 14 and 20 Under Stevens in View of Netherton et al. (US 4,900,309)**

Netherton discloses a needle shield 10 that comprises a planar disc-shaped member having a central opening 12. A hypodermic needle cover 18 extends from the bottom hub 14 of the disc-shaped member. The needle shield also has a number of ribs 40 at its peripheral rim 36 that are meant to facilitate the gripping of shield 10 for insertion over needle cover 18. Ribs 40 also are meant to prevent rolling of shield 10 (column 3, line 63 to column 4, line 4).

Claim 2 depends from claim 1 and defines the finger grasp means to comprise a wingnut (80) that has a bore that fits over a portion of the needle cover. A plurality of slots (90) are formed lengthwise along the inner circumferential surface of the bore, with each slot riding on a corresponding rib (32) formed longitudinally along substantially the length of the needle cover [0053-0055; Figs. 11a-11d].

The Netherton device is a not a wingnut. Indeed, a conventional reading of Netherton clearly shows that the planar structure of the Netherton device is not a wingnut. Rather, the Netherton device is a needle shield that does not have a plurality of slots along its inner circumferential surface that ride on corresponding ribs along the length of a needle cover. And given that Netherton discloses a needle shield having a sheath 18, it is submitted that a person skilled in the art would not have combined Netherton with Stevens since the Netherton shield is used to cover a contaminated needle (after use) whereas the

Stevens device is a needle hub assembly that requires its needle cover to be broken off from the needle hub before use.

Claim 3 depends from claim 2 and further defines that each wing (82, 84) of the wingnut has a leg (96, 98) supported by an upper surface of a collar (74) rotatably mounted to the neck of the body. The wingnut is fixedly secured to the needle cover, and a housing (72) extends from the collar and pivotable to a position in alignment along the longitudinal axis of the body [0056].

Neither Stevens nor Netherton discloses anything similar to the subject matter of claim 3, as neither of those references discloses any wingnut that has a wing that has a leg, and/or that the leg is supported by an upper surface of a collar rotatably mounted to the neck of the body.

Claim 14 depends from claim 11, and it defines the finger grasp means to comprise a ring having a plurality of wings (82, 84) that extend away from the outer wall (36) of the ring, and a plurality of slots along its inner wall. Claim 14 also includes limitations that are similar to those of claims 2 and 3 discussed above.

Neither Stevens nor Netherton discloses a ring that has a plurality of wings that extend away from its outer wall, and that the ring has a plurality of slots along its inner wall.

Claim 20 depends from claim 18 and defines the finger grasp means to be a wingnut (80). Neither Stevens nor Netherton discloses a wingnut.

In view of the above discussion, appellants submit that dependent claims 2, 3, 14 and 20 each are separately patentable over the cited prior art.

#### **IV. 103(b) Rejection of Claims 9, 12 and 13 Under Stevens in View of Newby (US 6,436,086)**

The patentability of claims 9, 12 and 13 stands or falls with the patentability of the claims from which they depend.

**Summation**

For the reasons pointed out above, appellants submit that the pending claims in the present application are patentability distinguishable over the cited prior art. The Board accordingly is respectfully requested to reverse the examiner's rejections.

Respectfully submitted,

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## **CLAIMS APPENDIX**

1. Apparatus, comprising:

a one piece cylindrical body having an opening at one end through which a fluid storage tube is insertable and a neck that has an elongate needle cover integrally extending therefrom, said cover being integrally joined to said neck at a weakened joint, finger grasp means coupled to said cover at a desired location along the length of said cover to amplify the torque force applied by a user to said cover when the user applies a predetermined torque to said finger grasp means to rotate said cover relative to said body to separate said cover from said neck at said weakened joint, said predetermined torque if applied anywhere along the length of said cover whereto said finger grasp means is not coupled would fail to separate said cover from said neck, said neck having an aperture dimensioned to accept a needle hub.

2. Apparatus of claim 1, wherein said finger grasp means comprises a wing nut having a bore adapted to fit over the needle cover of said body at a portion of said cover, a plurality of slots formed lengthwise along the inner circumferential surface of said bore, each slot riding on a corresponding rib formed longitudinally along substantially the length of said needle cover.

3. Apparatus of claim 2, wherein each wing of said wing nut has a leg supported by an upper surface of a collar rotatably mounted to the neck of the body, said wing nut being fixedly secured to said needle cover, a housing extending from said collar and pivotable to a position in alignment along the longitudinal axis of said body.

4. (Withdrawn) Apparatus of claim 1, wherein said finger twist means comprises a wing nut integrally formed at a portion of said needle cover, each of the wings of said wing nut

having a leg, the legs of said wings and a plurality of other legs extending downwards from said wing nut resting on an upper surface of a collar rotatably mounted to the neck of the body, a housing extending from said collar, said housing pivotable to a position in alignment along the longitudinal axis of said cylindrical body.

5. Apparatus of claim 1, wherein said neck comprises a first portion of a lock mechanism, and said needle hub comprises a second portion of said lock mechanism, wherein when said needle hub is inserted to said neck through said aperture, said first and second portions of said lock mechanism coact to fixedly maintain said needle assembly to said neck.
6. Apparatus of claim 1, wherein said needle hub is a part of a needle hub assembly comprising a base having a double ended needle extending therethrough, said needle hub including a proximal section having at least one catch and a distal section that is dimensioned to extend from a distal end of said neck when said needle hub is fully inserted to said aperture, said catch snappingly latching to a side orifice at said neck when said assembly is fully inserted to said aperture.
7. Apparatus of claim 1, wherein said weakened joint integrally joining said needle cover to said neck of said body is manufactured to withstand up to approximately 60 ounce inches of torque before breaking; and wherein said needle cover, once separated from said neck at said joint, is not attachable back to said neck.
8. Apparatus of claim 1, wherein said needle cover is separable from said body when said predetermined torque applied to said finger grasp means is less than approximately 60 ounce inches.

9. Apparatus of claim 1, wherein said needle hub is a part of a needle hub assembly comprising a double ended needle, and wherein once said needle cover is separated from said neck at said joint to expose an end of said needle extending from said needle hub, a needle protection housing pivotally connected to a collar rotatably mounted to said neck is movable to cover said end of said needle to thereby prevent said end of said needle from being further exposed.

10. Apparatus of claim 1, wherein said finger grasp means comprises at least one wing integrally extending transversely from said needle cover at the desired location.

11. A needle holder assembly, comprising:

a cylindrical body having

an opening at one end through which a fluid storage tube is insertable,

a neck having one lock mechanism formed transverse to a side thereof,

an elongate cover having a longitudinal length integrally extending from said neck and joined to said neck at a weakened joint, and

finger grasp means fixedly mounted to a desired location along the length of said elongate cover, said finger grasp means having at least one wing extending away from said elongate cover;

a needle hub assembly having

a proximal section and a distal section,

a double ended needle extending through said distal and proximal sections,

and

an other lock mechanism formed at the outer surface of said proximal section;

wherein said needle hub assembly is fixedly fitted within said body with at least said proximal section fitted within said neck and said one and other lock mechanisms in a locking relationship; and

wherein said cover is separable from said neck at said weakened joint when a predetermined torque is applied to said wing relative to either said body or said neck.

12. Needle holder assembly of claim 11, further comprising:

a collar rotatably mounted about said neck;

a housing hingedly attached to said collar and rotatable about said neck;

wherein after said cover is separated from said neck, said housing is pivotable to a position in substantial alignment with the one end of said double ended needle extending from said distal section of said needle hub assembly for covering said one end of said double ended needle.

13. Needle holder assembly of claim 11, wherein said housing comprises at least one hook mechanism for fixedly grasping and maintaining said one end of said double ended needle within said housing when said housing is pivoted to cover said one end of said double ended needle.

14. Needle holder of claim 11, wherein said finger grasp means comprises a ring having a plurality of wings extending away from the outer wall of said ring, said wings each having a lower leg that rests on an upper surface of said collar, said ring including a plurality of slots along its inner wall that guidedly fit to corresponding ribs extending longitudinally along the length of said needle cover when said ring is fitted to said needle cover, said ring further having a plurality of extensions at its inner wall in contact with said needle cover.

15. (Allowable) Needle holder assembly of claim 11, wherein said one lock mechanism comprises a pair of orifices formed transversely at opposite sides of said neck and wherein said other lock mechanism comprises a pair of catches formed at opposite sides of the outer surface of said proximal section, each of said catches latching onto a corresponding one of said orifices when said needle hub assembly is inserted to said body and said proximal section is press fitted to said neck; and

wherein said neck has an aperture dimensioned to accept said proximal section and at least a portion of said distal section of said needle hub assembly.

16. Needle holder assembly of claim 11, wherein said weakened joint integrally joining said needle cover to said neck of said body is manufactured to withstand up to approximately 60 ounce inches of torque before breaking; and wherein said needle cover, once separated from said neck at said joint, is not attachable back to said neck.

17. Needle holder assembly of claim 11, wherein said finger grasp means is integral to said cover at the desired location.

18. A one piece molded needle holder, comprising: a cylindrical body having a cavity and an opening at one end through which a fluid storage tube is insertable to said cavity, said body ending with a neck having at least one orifice formed transverse to a side thereof, said neck having an aperture smaller in dimension than said cavity, a needle cover having a longitudinal length integrally joined to and extending from the end of said neck away from said body, a notch formed circumferentially about the junction where said neck is joined to said cover to effect a weakened joint, finger grasp means coupled to a desired location along the length of said needle cover to enable a user to twist off said needle cover from said neck by applying a predetermined torque thereto.

19. (Allowable) Needle holder of claim 18, wherein said neck comprises a pair of orifices formed at opposite sides thereof, said needle holder further comprising a collar having a housing pivotably attached thereto rotatably mounted about said neck, said housing pivotable to a position in alignment along the longitudinal axis of said holder for covering a needle extending from a needle assembly mated to said neck, a hook integral in said housing fixedly holding said needle once said housing is pivoted to said alignment position.

20. Needle holder of claim 18, wherein said finger grasp means comprises a wing nut, and said needle cover is separable from said body when said predetermined torque applied to said wing nut is less than approximately 60 ounce inches; and wherein said needle cover, once separated from said neck at said joint, is not attachable back to said neck.

21. (Allowable) A one piece molded needle hub assembly to be used with the molded needle holder of claim 18, comprising: a proximal section and a distal section, said proximal section dimensioned to fit to the aperture of the neck of said holder, a double ended needle extending through said distal and proximal sections, a pair of catches formed at opposite sides of the outer circumference of said proximal section, and a through slot formed in said proximal section behind each of said catches to enable flexible movements of said catch transversely to said proximal section.

22. (Withdrawn) A method of manufacturing a needle holder, comprising the steps of:

- forming a cylindrical body having an opening at one end through which a fluid storage tube is insertable into the cavity of said body;
- forming a neck integral to said body having an aperture smaller in diameter than said opening of said body;

- c) forming at least one orifice transverse to a side of said neck for accepting a catch from a needle hub to be inserted into said neck;
- d) extending an elongate needle cover integrally from said neck; and
- e) coupling a finger grasp means to said needle cover.

23. (Withdrawn) Method of claim 22, wherein said finger grasp means comprises a wing nut, said method further comprising the step of:

notching or thinning the junction where said needle cover is integrally extended from said neck so that a given torque applied to said wing nut relative to either said neck or said body will separate said needle cover from said neck.

24. (Withdrawn) A method of manufacturing a needle holder, comprising the steps of:

- a) forming a cylindrical body having an opening at one end through which a fluid storage tube is insertable into the cavity of said body;
- b) forming a neck integral to said body having an aperture smaller in diameter than said opening of said body;
- c) forming one lock mechanism transverse to a side of said neck;
- d) extending an elongate needle cover integrally from said neck;
- e) coupling a finger grasp means to said needle cover;
- f) forming a needle hub assembly about a double ended needle with one end of said needle extending from its distal end and an other end of said needle extending from its proximal end;
- g) forming an other lock mechanism at said needle hub assembly;
- h) inserting said needle hub to the cavity of said body through said opening of said body; and

I) press fitting said needle hub to said aperture of said neck until said one and other lock mechanisms coact to fixedly hold said needle hub to said neck with said one needle end extending from said needle hub into said needle cover and said other needle end extending from said needle hub into the cavity of said body where said fluid storage tube is to be inserted.

25. (Withdrawn) Method of claim 24, wherein said finger grasp means comprises a wing nut, said method further comprising the step of:

notching or thinning the junction where said needle cover is integrally joined to said neck so that a torque of less than approximately 60 ounce inches or greater applied to said wing nut relative to either said neck or said body will separate said needle cover from said neck.

26. (Withdrawn) Method of claim 24, wherein said step c comprises the step of forming a pair of orifices at opposite sides of said neck, and wherein said step g comprises the step of forming a pair of catches at opposite sides of said needle hub; wherein said step e further comprises the step of press fitting said needle hub into said aperture of said neck until said catches each latch onto a corresponding one of said orifices to fixedly retain said needle hub to said neck.

27. (Withdrawn) Method of claim 24, wherein said step e comprises integrally forming said finger grasp means and said cover, said finger grasp means being a wing nut.

## **EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.